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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,347	03/30/2004	Gilbert Lavielle	S403DIV	5023

25666 7590 06/10/2005

THE FIRM OF HUESCHEN AND SAGE
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KALAMAZOO, MI 49007

EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,347

Applicant(s)

LAVIELLE ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/400,358.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

S.G.D.

DETAILED ACTION

1. Claims 19-24 are pending.

Claim Rejections - 35 USC § 112

2. The rejection for Claims 19-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon reconsideration in view of Applicant's Remarks.

Claim Rejections - 35 USC § 112

3. The scope enablement rejection for Claims 19-24 under 35 U.S.C. 112, first paragraph is maintained for reasons of record.

The Declaration of Dr. Millan and the references therein have been fully considered but fail to obviate the rejection.

The specification, while being enabling for treating migraine, depression, bulimia, anorexia and for inhibiting penile erection, does not reasonably provide enablement for all the other disorders as recited.

Example 6 and the cited references by Berendsen and Millan support the inhibition of penile erections with a 5-HT_{2c} receptor antagonist, there is no indication or suggestion that the 5-HT_{2c} receptor antagonist compound would treat any other disorders of the libido and sexual dysfunctions, such as impotence. While amesergide (LY 237733) is in phase II clinical trials, the structure of the compound is quite removed from the instant. In view of the high degree of unpredictability in the 5-HT receptor art, one of ordinary skill in the art would have no basis to extrapolate the results of amesergide to the structurally removed compound of the invention.

The references by O'Neill, Reavill, Herrick-Davis, Wood only *suggest* the potential of 5-HT_{2c} receptor antagonist in schizophrenia.

The effects of ritanserin on sleep disturbances of dysthymic patients have been reported by Paiva, more specifically, ritanserin increases the Slow Wave Sleep. However, ritanserin is a

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non-selective 5-HT_{2A/2C} antagonist (Popova et al. PTO-1449). Furthermore, questions remain with regard to the physiological significance of the 5HT₂ receptor-mediated deep SWS regulation, the site(s) and the mechanism of this regulation (Dugovic C. Summary, PTO-1449). Even though 5-HT_{2c} antagonist may increase SWS, there is no teaching or suggestions that it will treat any other sleep disorders, such as narcolepsy.

The cited references in support of the involvement of 5-HT_{2c} receptor in learning and memory are not based on the use of a selective 5-HT_{2c} receptor antagonist, and therefore fail to lend support to the use of the inventive compound for treating any cognitive disorders, especially delirium, dementia and amnesia.

While 5-HT_{2c} receptor antagonists are of potential use in the treatment of Parkinson's disease (Fox et al. PTO-1449), it is still only 'a matter of potentially great interest' at the time of the invention.

Since the instant 'cognitive disorders', 'appetite disorders', 'impulsive disorders', 'sleep disorders', and 'disorders of the libido and sexual dysfunction' etc. are general classes of disorders embracing opposing and conflicting conditions arising from diverse origins, it is impossible to use a single 5HT_{2c} receptor antagonist compound of the instant to treat all these contradictory conditions. Applicant's assertion that all the inventive compounds would be effective in treating schizophrenia, Parkinson's disease, any cognitive disorders (arising from different origins involving different mechanisms, including delirium, dementia and amnesia), any appetite disorder (including the conflicting hyperphagia and anorexia), any sleep dysfunction (including the conflicting insomnia and narcolepsy) or any disorders of the libido and sexual dysfunctions (including the conditions involving the opposing inhibitory and stimulatory sexual behaviors) does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the art, and the limited working examples.

Since insufficient teaching and guidance have been provided, one of ordinary skill in the art, even with high level of skill, would not be able to use the inventive compound for treating all the disorders as claimed without undue experimentation except for treating migraine, depression, bulimia, anorexia and for inhibiting penile erection.

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Conclusion

4. No claims are allowed.

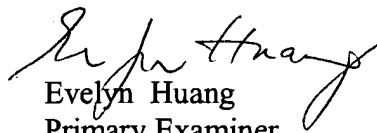
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
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